IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS MANUFACTURING GMBH, and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Biogen Inc. ("Biogen Inc."), Biogen Swiss Manufacturing GmbH ("BSM") (together "Biogen"), and Alkermes Pharma Ireland Limited ("Alkermes Pharma") (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Zydus") of Abbreviated New Drug Application ("ANDA") No. 218596 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Vumerity® (diroximel fumarate) delayed-release capsules for oral use, 231 mg ("Zydus's ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,669,281 ("the '281 patent"); 9,090,558 ("the '558 patent"); and 10,080,733 ("the '733 patent") (collectively "the Asserted Patents"). Zydus notified Plaintiffs that it had submitted this ANDA by a letter dated May 25, 2023 ("Notice Letter"). Upon information and belief, if

approved by FDA, Zydus's ANDA Product will be marketed as a competing product to Vumerity®, a product developed by Plaintiffs for the treatment of relapsing forms of multiple sclerosis (MS).

PARTIES

2. Biogen Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 225 Binney Street, Cambridge, MA 02142.

3. BSM is a limited liability company organized and existing under the laws of Switzerland, having a place of business at Neuhofstrasse 30, Baar, 6340, Switzerland.

4. Alkermes Pharma is a private limited company organized and existing under the laws of The Republic of Ireland, having a place of business at 1 Burlington Road, Connaught House, Dublin, Ireland. Alkermes Pharma is a wholly-owned subsidiary of Alkermes Ireland Holdings Limited, which is a wholly-owned subsidiary of Alkermes Public Limited Company.

5. Upon information and belief, Defendant Zydus Worldwide DMCC is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeriah Lakes Tower, P.O. Box 113536, Dubai, United Arab Emirates.

6. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

7. Upon information and belief, Zydus Lifesciences Limited is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

8. Upon information and belief, Zydus Worldwide submitted ANDA No. 218596 to

FDA, and Zydus USA is acting as an agent for Zydus Worldwide with respect to Zydus's ANDA Product.

9. Upon information and belief, following any approval of Zydus' ANDA No. 218596, Zydus Worldwide, Zydus USA, and Zydus Lifesciences will act in concert to distribute and sell Zydus's ANDA Product through the United States, including within Delaware.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Zydus Worldwide is subject to personal jurisdiction in Delaware because among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Worldwide is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. Zydus USA is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus USA is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

13. Zydus Lifesciences is subject to personal jurisdiction in Delaware because, among

other things, Zydus Lifesciences, itself and through its wholly owned indirect subsidiaries Zydus Worldwide and Zydus USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Lifesciences, itself and through its wholly owned indirect subsidiaries Zydus Worldwide and Zydus USA, is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware. In addition, Zydus Lifesciences is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Zydus Worldwide and Zydus USA, and therefore the activities of Zydus Worldwide and Zydus USA in this jurisdiction are attributed to Zydus Lifesciences.

14. Upon information and belief, Zydus has sought approval in ANDA No. 218596 to distribute Zydus's ANDA Product in the United States, including in Delaware and will do so upon approval of ANDA No. 218596. The filing of ANDA No. 218596 is therefore tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and indicates that Zydus plans to engage in the marketing of Zydus's ANDA Product in Delaware.

15. Upon information and belief, if ANDA No. 218596 is approved, Zydus will directly or indirectly market and/or sell Zydus's ANDA Product within the United States, including in Delaware, consistent with Zydus's practices for the marketing and distribution of other pharmaceutical products on its own and/or through its affiliates.

16. Upon information and belief, if ANDA No. 218596 is approved, Zydus's ANDA Product, under the direction and control of physicians practicing in Delaware, will be administered to patients in Delaware. These activities, as well as Zydus's marketing, selling, and/or distributing

of Zydus's ANDA Product, would have a substantial effect within Delaware and would constitute infringement of the Asserted Patents in the event that Zydus's ANDA Product is approved before the Asserted Patents expire.

17. For the reasons described above, among others, the filing of ANDA No. 218596 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Zydus does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Zydus.

18. Venue is proper in this judicial district as to Zydus Worldwide under 28 U.S.C. §§ 1391 and 1400(b) because Zydus Worldwide is incorporated in the United Arab Emirates and may be sued in any judicial district in the United States.

19. Venue is proper in this judicial district as to Zydus Lifesciences under 28 U.S.C. §§ 1391 and 1400(b) because Zydus Lifesciences is incorporated in the Republic of India and may be sued in any judicial district in the United States.

20. Venue is proper in this judicial district as to Zydus USA under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus USA is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district for the purpose of this case. Zydus USA has consented to venue in this judicial district in numerous patent litigations, including but not limited to the following actions: *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 22-cv-01386-GBW (D. Del.); *Novo Nordisk Inc., et al. v Zydus Worldwide DMCC, et al.*, C.A. No. 22-297-CFC (D. Del.); *Astrazeneca AB, et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 21-550-RGA (D. Del.).

BACKGROUND

21. Vumerity® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

22. Biogen sells Vumerity® in the United States pursuant to New Drug Application ("NDA") No. 211855, which has been approved by FDA.

23. Biogen Inc. is the holder of approved NDA No. 211855 for Vumerity®.

24. The '281 patent, titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases," was duly and legally issued on March 11, 2014. A copy of the '281 patent is attached as Exhibit A.

25. Alkermes Pharma is the assignee of the '281 patent.

26. BSM is the exclusive licensee of the '281 patent.

27. There is an actual case or controversy between the parties regarding Zydus's liability for its infringement of the '281 patent.

28. The '558 patent, titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases," was duly and legally issued on July 28, 2015. A copy of the '558 patent is attached as Exhibit B.

29. Alkermes Pharma is the assignee of the '558 patent.

30. BSM is the exclusive licensee of the '558 patent.

31. There is an actual case or controversy between the parties regarding Zydus's liability for its infringement of the '558 patent.

32. The '733 patent, titled "Prodrugs of Fumarates and Their Use in Treating Various Diseases," was duly and legally issued on September 25, 2018. A copy of the '733 patent is

attached as Exhibit C.

33. Alkermes Pharma is the assignee of the ’733 patent.

34. BSM is the exclusive licensee of the ’733 patent.

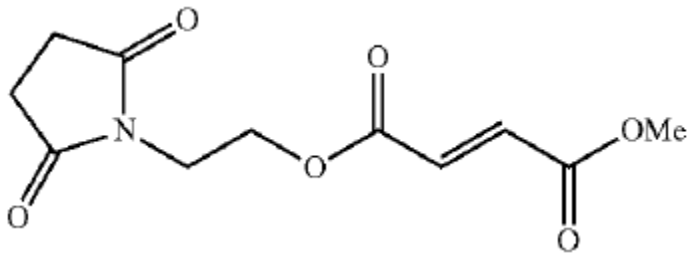
35. There is an actual case or controversy between the parties regarding Zydus’s liability for its infringement of the ’733 patent.

36. This action is being filed within 45 days of Plaintiffs’ receipt of Zydus’s Notice Letter.

COUNT I
(Infringement of the ’281 Patent)

37. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

38. Claim 1 of the ’281 patent covers “[a] compound having the formula:



or a pharmaceutically acceptable salt thereof.”

39. Upon information and belief, Zydus’s ANDA Product is covered by one or more claims of the ’281 patent, including at least claim 1.

40. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus’s ANDA Product will infringe one or more claims of the ’281 patent, including at least claim 1, either literally or under the doctrine of equivalents.

41. Zydus did not assert in its Notice Letter a basis for any assertion that Zydus’s ANDA Product would not infringe any claim of the ’281 patent.

42. Upon information and belief, Zydus filed as part of ANDA No. 218596 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the claims of the '281 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Zydus's ANDA Product.

43. The purpose of filing ANDA No. 218596 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '281 patent.

44. Zydus's submission of ANDA No. 218596 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '281 patent is an act of infringement of the '281 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Zydus intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto, *i.e.*, prior to the expiration of the '281 patent.

46. Upon information and belief, Zydus has knowledge of the '281 patent at least because the '281 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Biogen's Vumerity® drug product. Notwithstanding this knowledge, Zydus continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto.

47. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the ’281 patent when ANDA No. 218596 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the ’281 patent. Further upon information and belief, Zydus plans and intends to, and will, do so immediately and imminently upon approval.

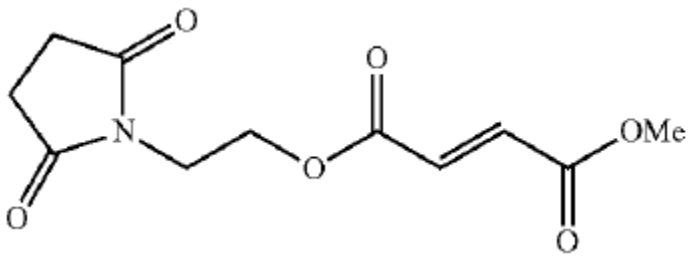
48. The foregoing actions by Zydus constitute and/or will constitute infringement of the ’281 patent and active inducement of infringement of the ’281 patent, either literally or under the doctrine of equivalents.

49. Unless Zydus is enjoined from infringing the ’281 patent and actively inducing infringement of the ’281 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’558 Patent)

50. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

51. Claim 1 of the ’558 patent covers “[a] method of treating multiple sclerosis in a subject in need thereof, comprising administering to the subject a therapeutically effective amount of a compound having the formula:



or a pharmaceutically acceptable salt thereof.”

52. Upon information and belief, use of Zydus’s ANDA Product is covered by one or more claims of the ’558 patent, including at least claim 1.

53. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product will infringe one or more claims of the '558 patent, including at least claim 1, either literally or under the doctrine of equivalents.

54. Zydus did not assert in its Notice Letter a basis for any assertion that the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would not infringe any claim of the '558 patent.

55. Upon information and belief, Zydus filed as part of ANDA No. 218596 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. 355(j)(2)(A)(vii)(IV), asserting that the claims of the '558 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Zydus's ANDA Product.

56. The purpose of filing ANDA No. 218596 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '558 patent.

57. Zydus's submission of ANDA No. 218596 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '558 patent is an act of infringement of the '558 patent under 35 U.S.C. § 271(e)(2)(A).

58. Upon information and belief, Zydus intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto, *i.e.*, prior to the expiration of the '558 patent.

59. Upon information and belief, Zydus has knowledge of the '558 patent at least because the '558 patent is listed in the FDA's *Orange Book: Approved Drug Products with*

Therapeutic Equivalence Evaluations for Biogen's Vumerity® drug product. Notwithstanding this knowledge, Zydus continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto.

60. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '558 patent when ANDA No. 218596 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '558 patent. Further upon information and belief, Zydus plans and intends to, and will, do so immediately and imminently upon approval.

61. Upon information and belief, Zydus knows that Zydus's ANDA Product is especially made or adapted for use in infringing the '558 patent, and that Zydus's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to infringement of the '558 patent immediately and imminently upon approval of ANDA No. 218596 and any amendments thereto.

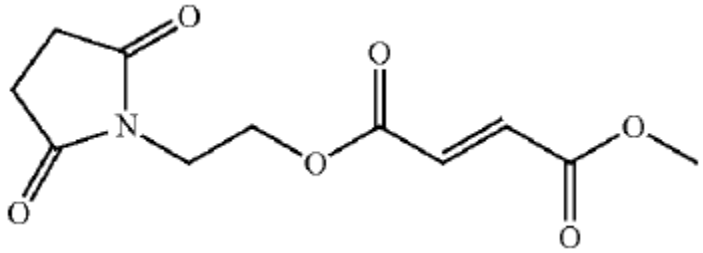
62. The foregoing actions by Zydus constitute and/or will constitute infringement of the '558 patent, active inducement of infringement of the '558 patent, and contribution to the infringement by others of the '558 patent, either literally or under the doctrine of equivalents.

63. Unless Zydus is enjoined from actively inducing infringement of the '558 patent and contributing to the infringement by others of the '558 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '733 Patent)

64. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

65. Claim 1 of the '733 patent covers "[a] crystalline form of a compound having the formula:



having an X-ray powder diffraction pattern comprising peaks, in terms of degrees 2-theta±0.2 degrees, at 11.6, 21.0, 24.3, 27.4, and 27.9 when using a Cu X-ray source."

66. Upon information and belief, Zydus's ANDA Product is covered by one or more claims of the '733 patent, including at least claim 1.

67. Upon information and belief, the manufacture, sale, offer for sale, or importation of Zydus's ANDA Product, or the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product, will infringe one or more claims of the '733 patent, including at least claim 1, either literally or under the doctrine of equivalents.

68. Zydus did not assert in its Notice Letter a basis for any assertion that Zydus's ANDA Product, or the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product, would not infringe any claim of the '733 patent.

69. Upon information and belief, Zydus filed as part of ANDA No. 218596 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the claims of the '733 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Zydus's ANDA Product.

70. The purpose of filing ANDA No. 218596 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '733 patent.

71. Zydus's submission of ANDA No. 218596 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '733 patent is an act of infringement of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

72. Upon information and belief, Zydus intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto, *i.e.*, prior to the expiration of the '733 patent.

73. Upon information and belief, Zydus has knowledge of the '733 patent at least because the '733 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Biogen's Vumerity® drug product. Notwithstanding this knowledge, Zydus continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 218596 and any amendments thereto.

74. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '733 patent when ANDA No. 218596 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '733 patent. Further upon information and belief, Zydus plans and intends to, and will, do so immediately and imminently upon approval.

75. Upon information and belief, Zydus knows that Zydus's ANDA Product is especially made or adapted for use in infringing the '733 patent, and that Zydus's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and

intends to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of ANDA No. 218596 and any amendments thereto.

76. The foregoing actions by Zydus constitute and/or will constitute infringement of the '733 patent, active inducement of infringement of the '733 patent, and contribution to the infringement by others of the '733 patent, either literally or under the doctrine of equivalents.

77. Unless Zydus is enjoined from infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement by others of the '733 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Zydus has infringed the Asserted Patents and will infringe, actively induce infringement of, and/or contribute to infringement by others of the Asserted Patents;

(b) A judgment ordering that the effective date of any FDA approval for Zydus to make, use, offer for sale, sell, market, distribute, or import Zydus's ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from making, using, selling, offering for sale, marketing, distributing, or importing Zydus's ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Zydus's ANDA Product, or any product the use of which infringes

the Asserted Patents, prior to the expiration date of the Asserted Patents, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the Asserted Patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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